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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,456	01/17/2007	Ernest Balestracci	84637.010702	1342
32361 7590 01/29/2008 GREENBERG TRAURIG, LLP MET LIFE BUILDING 200 PARK AVENUE NEW YORK, NY 10166			EXAMINER SMYTH, ANDREW P	
			ART UNIT 2881	PAPER NUMBER
			NOTIFICATION DATE 01/29/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	Application No. 10/597,456	Applicant(s) BALESTRACCI ET AL.	
	Examiner Andrew Smyth	Art Unit 2881	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33, 38 and 39 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 29-33, 38 and 39 is/are rejected.
- 7) ☒ Claim(s) 12-28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Response to Restriction***

1. Applicants elect claims 1-33 and 38-39 drawn to a "pharmaceutical container."  
Applicants reserve their right to prosecute any and all remaining claims in subsequent divisional applications filed while the present application is pending.

### ***Claim Objections***

1. Claims 12-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 7-8, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergner (US 4,562,829).

Regarding applicant's claim 1, Bergner discloses: An improved pharmaceutical container for containing a pharmaceutical agent which is heated, subjected to increased pressure or radioactive, comprising: a.) an inlet arm, b.) a hollow column, and c.) an outlet arm, wherein the improvement comprises configuring the outlet arm so that it does not protrude into the hollow portion of the column, and support means to support the inlet arm and the outlet arm (figure 1, 24, 30, 28, 29); (abstract).

Regarding applicant's claim 2, Bergner discloses: 2. The improved pharmaceutical container of claim 1, wherein the container is constructed of a material which is resistant to radiation (inherent in the device).

Regarding applicant's claim 7, Bergner discloses: The improved pharmaceutical container of claim 1 or 2, further comprising two stoppers which form tight seals with and prevent leakage from an open top end and an open bottom end of the column, wherein said stoppers are made of a material which is resistant to radiation (inherent in the device) , optionally further comprising a packing material which optionally contains a pharmaceutical agent (figure 1, 28, see top and bottom of column).

Regarding applicant's claim 8, Bergner discloses: The improved pharmaceutical container of claim 7, wherein the bottom stopper takes up substantially all of the space at the open bottom end of the column, without blocking the outlet arm, so as to reduce the amount of the dead volume at the bottom of the column (figure 1, 28, see bottom of column).

Regarding applicant's claim 29, Bergner discloses: The improved pharmaceutical container of claim 1, for generating rubidium-82 (abstract).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3-4 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergner (US 4,562,829).

In regards to claims 3-4 and 9-10 the device differs from the claimed invention by not showing the element comprises a material selected from the group consisting of polypropylene, PP 13R9A polypropylene, isoprene/chlorobutyl, bromobutyl and FM 140/0. It would have been obvious for the element to be composed of a material selected from the group consisting of polypropylene, PP 13R9A polypropylene, isoprene/chlorobutyl, bromobutyl and FM 140/0, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. In re Leshin, 125 USPQ 416.

5. Claims 5-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergner (US 4,562,829) in light of Czaplinski et al. (US 3,920,995).

Regarding applicant's claims 5, 6, and 11, Bergner discloses: the elements of applicant's claims 1 and 7-8 that claims 5, 6, and 11 depend upon, see above.

Regarding applicant's claim 5, Bergner lacks: An improved pharmaceutical container of claim 1 or 2, wherein a notch is provided in the hollow column at the point where the outflow arm intersects the hollow column.

Yet, Czaplinski teaches: An improved pharmaceutical container of claim 1 or 2, wherein a notch is provided in the hollow column at the point where the outflow arm intersects the hollow column (figure 4, 40).

Regarding applicant's claim 6, Bergner lacks: The improved pharmaceutical container of claim 1 or 2, further comprising a basket receptacle area inside the column for receiving a basket where the inlet arm intersects the column, said basket receptacle area further comprising one or more notches, said notches configured to cooperate with one or more protrusions on a basket to be inserted into the basket receptacle area in such a way so as to insure that the basket is properly seated in the basket receptacle area.

Yet, Czaplinski teaches: The improved pharmaceutical container of claim 1 or 2, further comprising a basket receptacle area inside the column for receiving a basket where the inlet arm intersects the column, said basket receptacle area further comprising one or more notches, said notches configured to cooperate with one or more protrusions on a basket to be inserted into the basket receptacle area in such a way so as to insure that the basket is properly seated in the basket receptacle area (column 2, lines 45- 59).

Regarding applicant's claim 11, Bergner lacks: The improved pharmaceutical container of claim 7 or 8, wherein each of said stoppers comprises a top cylindrical portion and a bottom cylindrical portion, said bottom cylindrical portion having a diameter sufficient to insure a tight seal between the stopper and the cylinder interface, and said top cylindrical portion having a diameter greater than the bottom cylindrical portion.

Yet, Czaplinski teaches: The improved pharmaceutical container of claim 7 or 8, wherein each of said stoppers comprises a top cylindrical portion and a bottom cylindrical portion, said bottom cylindrical portion having a diameter sufficient to insure a tight seal between the stopper and the cylinder interface, and said top cylindrical portion having a diameter greater than the bottom cylindrical portion (figure 4, 17, 16).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the elements of pharmaceutical container, as disclosed by Bergner, with basket receptacle and stoppers with top cylindrical portion having a diameter greater than the bottom cylindrical portion, as taught by Czaplinski, to utilize as a receptacle and sealed ends for the pharmaceutical container's hollow column.



6. Claims 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergner (US 4,562,829) in light of Nijsen et al.(US 6,373,068).

Regarding applicant's claim 30, Bergner discloses: the elements of applicant's claim 1 that claim 30 depends upon, see above.

However, Bergner lacks: The improved pharmaceutical container of claim 1, further comprising a first connector tube which attaches to the inlet arm via a Luer lock, and a second connector tube which attaches to the outlet arm via a Luer lock, wherein a portion of each Luer lock is affixed to each of the connector tubes and another portion of the Luer locks is affixed to each of the inlet arm and outlet arm.

Nijsen teaches: The improved pharmaceutical container of claim 1, further comprising a first connector tube which attaches to the inlet arm via a Luer lock, and a second connector tube which attaches to the outlet arm via a Luer lock, wherein a portion of each Luer lock is affixed to each of the connector tubes and another portion of the Luer locks is affixed to each of the inlet arm and outlet arm (column 1, line 65 to column 2, line 3).

Regarding applicant's claim 31, Bergner discloses: The improved pharmaceutical container of claim 30, wherein the connector tubes and the Luer lock portions attached to the connector tubes are made of materials which are resistant to radiation..

However, Bergner lacks: Luer lock.

Nijsen teaches: Luer lock (column 1, line 65 to column 2, line 3).



Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the elements of pharmaceutical container, as disclosed by Bergner , with Luer locks , as taught by Nijsen , to utilize as a lock for the arms .

1. Claims 32-33 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergner (US 4,562,829) in light of Nijsen et al.(US 6,373,068).

In regards to claims 32-33 and 38-39, the device differs from the claimed invention by not showing the element comprises a material selected from the group consisting of radiation resistant polyvinyl chloride, PVC 2232 A/R-78S clear 030X, radiation resistant polyvinyl chloride, and an absorbent material as GP- 100. It would have been obvious for the element to be composed of a material selected from the group consisting of radiation resistant polyvinyl chloride, PVC 2232 A/R-78S clear 030X, radiation resistant polyvinyl chloride, and an absorbent material as GP- 100, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. In re Leshin, 125 USPQ 416.

### ***Conclusion***

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See references cited.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Smyth whose telephone number is 571-270-1746. The examiner can normally be reached on 7:30AM - 5:00PM; Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Kim can be reached on 571-272-2293. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A.S.

  
ROBERT KIM  
SUPERVISORY PATENT EXAMINER